



ENZYMATIC THERAPY

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July 13, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Alluna Sleep is an herbal supplement that can relieve occasional sleeplessness.*	Valerian Root Extract, Hops Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

7/13/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Financial Officer

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July 13, 2005

INTEGRATIVE THERAPEUTICS INC.™

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Tyler Encapsulations • Vitaline Formulas

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P: 920.469.9099 • F: 920.469.4418 (Phyto)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Alluna Sleep works by helping you relax, so you can drift off to sleep naturally.*	Valerian Root Extract, Hops Extract

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By: 

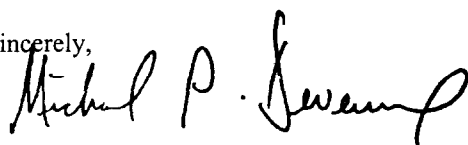
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Alluna Sleep has been clinically tested and shown to be effective in actually promoting your body's own natural sleep pattern – safely and gently.*	Valerian Root Extract, Hops Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	You can expect to wake up refreshed, with no groggy side effects, because you experience a natural, healthy sleep through the night.*	Valerian Root Extract, Hops Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Alluna Sleep helps your body maintain a healthy sleep pattern to provide you with long-term, consistent results.*	Valerian Root Extract, Hops Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Modern scientists believe that valerian's mechanism of action is its ability to interact with certain receptors in your body. This can help you relax better. It should be noted that the active constituents of valerian appear to weakly interact with these receptors. While exhibiting an effect on the receptors, valerian has not been associated with dependence or any kind of physical addiction because it has no lingering effect.*	Valerian Root Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Because the constituents of valerian weakly interact with the receptors, there is no lasting effect of valerian on the central nervous system. There is no residual effect that "lingers" in the body.*	Valerian Root Extract

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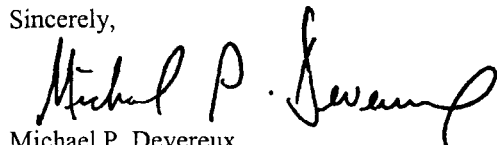
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Alluna has been shown to significantly promote a person's ability to stay asleep through the night. It may take a few nights to reap the full benefits.*	Valerian Root Extract, Hops Extract

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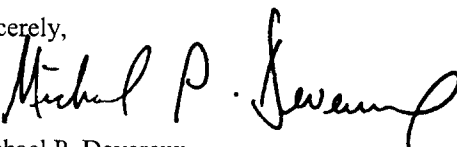
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	Wake up refreshed, not groggy*	Valerian Root Extract, Hops Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Alluna™ Sleep	For deep, high-quality sleep – naturally!*	Valerian Root Extract, Hops Extract

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Alluna™ Sleep	Improves healthy, long-term sleep patterns.*	Valerian Root Extract, Hops Extract

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Alluna™ Sleep	Non- habit forming alluna Sleep safely, gently and naturally helps you relax.*	Valerian Root Extract, Hops Extract

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Alluna™ Sleep	Relieves occasional sleeplessness and promotes your body's own long-term sleep pattern within just a few nights.*	Valerian Root Extract, Hops Extract

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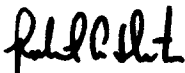
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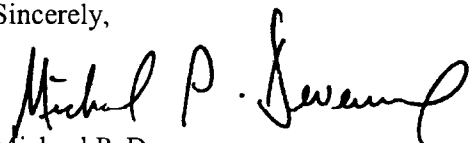
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